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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,591

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Michael J. Yaszemski

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EXAMINER

ASINOVSKY, OLGA

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,591	Applicant(s) YASZEMSKI ET AL.	
	Examiner OLGA ASINOVSKY	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-17 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 6-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 4, 5, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bajpai U.S. Patent 4,668,295.

3. Bajpai discloses surgical bone repair cement composition comprising polymeric materials comprising polyfunctional acids and bone mineral such as hydroxyapatite, column 1, lines 55-67 and column 2, line 25. The polyfunctional acids can be saturated or unsaturated, column 2, lines 2-3 and 10-32, including fumaric acid and succinic acid. The acids can be used in combination of unsaturated diacid and saturated diacid. The combination of these acids has advantage to control setting properties, column 2, lines 10-11. The combination of acids is readable in the present claim 1. Fumaric acid is readable in the present claim 2. Saturated diacid such as succinic acid, column 2, line 5, is readable in the present claim 4. The selected saturated acid such as succinic acid is inherently meet the statement being “compatible” with fumaric acid and poly(propylene dumarate) in the present claim 3. Hydroxyapatite is readable as a bone substitute bioactive ceramic in the present claims 1 and 5. The composition can include polymeric material, column 3, lines 45, 60. Polylactic acid and poly(meth)acrylic acid are compatible with the polyfunctional carboxylic acids for producing surgical cements. The

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polylactic acid and poly(meth)acrylic acid are readable for being polymeric matrix in the present claim 26. Bajpai discloses a surgical cement for bone substitute, column 3, lines 3-4. The statement that "the composition is suitable as a scaffold for tissue regeneration wherein the tissue is bone" in the present claims 29-30 is intended use of the analogous composition in Bajpai invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 27-28, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bajpai U.S. Patent 4,668,295 as applied to claims 1, 2, 3, 4, 5, 26, 29, 30 above, and further in view of Gerhart et al U.S. Patent 5,085,861.

Gerhart discloses bone cement composition comprising polymer matrix and bone repair hydroxyapatite, column 2, lines 31-36 and column 6, line 65. The polymer matrix is a biodegradable polyester formed from reaction of dicarboxylic acids and dihydric or polyhydric alcohols, column 2, lines 54-56. Dicarboxylic acids include succinic acid and fumaric acid, column 4, lines 56-57. The polyester is polypropylene glycol fumarate, column 5, lines 5-8. The polypropylene fumarate is readable in the present claims 3 and 27-32. The polyester can be crosslinked by additional of a free-radical initiator, column 6, lines 16-19, for the present claims 31 and 33. The composition can be used for bone repair embodiment, column 6, line 54, for the present claims 29-30.

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Both references disclose the analogous implant compositions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the surgical cement composition in Bajpai invention by including a polymeric matrix such as polypropylene fumarate by teaching in Gerhart invention to improve biocompatible resorbable surgical cement for repairing living bone, Gerhart, column 3, lines 46-61.

Allowable Subject Matter

6. Claims 6-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 13-17 are allowed. There is no found prior art wherein a macromer includes silane units, units derived from an unsaturated diacid having a carbon-carbon double bond, and units derived from a saturated diacid.

Drawings

8. The drawings are objected to because Figure 1b is indistinct and not readable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

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made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References have been considered. Bajpai reference is discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLGA ASINOVSKY whose telephone number is (571)272-1066. The examiner can normally be reached on 9:00 to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796

Olga Asinovsky
Examiner
Art Unit 1796